### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THERESA M. OWENS,

Plaintiff,

03 1798

CIVIL ACTION No.

ELI LILLY AND COMPANY,

v.

Defendant.

FILED

AUG 2 7 2003

# DEFENDANT ELI LILLY AND COMPANY'S MANCY MAYER WHITINGTON, CLERK ANSWER TO THE COMPLAINT

Defendant Eli Lilly and Company ("Lilly"), by its undersigned attorneys, answers the Complaint filed in this action as follows:

#### FIRST DEFENSE

Answers to each paragraph of the Complaint by Lilly are made without waiving, but expressly reserving all rights that Lilly may have to seek relief by appropriate motions directed to the allegations of the Complaint.

- 1. Whether jurisdiction exists in this court pursuant to 11 D.C. Code § 921 is a legal question to which no response is required. To the extent a response is required, however, Lilly denies the allegations contained in Paragraph 1 of the Complaint.
- 2. Lilly states that it did sell and distribute diethylstilbestrol in the District of Columbia. Lilly responds that the term "DES" includes many drug products including but not limited to diethylstilbestrol, and any admissions in this Answer are intended to refer only to diethylstilbestrol as it relates to Lilly. Lilly also states that it is doing business in the District of Columbia, that the U.S. Food and Drug Administration ("FDA") is headquartered in the District of Columbia, and that the FDA approved Lilly's sales of diethylstilbestrol and declared that the

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drug was generally recognized as safe by experts in the field for the uses at issue here. Except as already stated, Lilly denies the allegations contained in Paragraph 2 of the Complaint.

#### COUNT I (Negligence)

- 3. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first two sentences of Paragraph 3. Lilly states that following FDA approval of its Supplemental New Drug Application in 1947, Lilly manufactured and sold certain dosages of diethylstilbestrol. To the extent that a response is required, however, Lilly denies the allegations of Paragraph 3 of the Complaint.
  - 4. Lilly denies the allegations contained in Paragraph 4 of the Complaint.
  - 5. Lilly denies the allegations contained in Paragraph 5 of the Complaint.

### COUNT II (Strict Liability)

- 6. Lilly repeats and realleges its answers contained in Paragraphs 1 through 5 above.
- 7. Lilly denies the allegations contained in Paragraph 7 of the Complaint.
- 8. In response to the allegations contained in Paragraph 8, Lilly states that following FDA approval of its Supplemental New Drug Application in 1947, Lilly manufactured and sold certain dosages of diethylstilbestrol. Except as already stated, Lilly denies the allegations of Paragraph 8 of the Complaint.
- 9. Lilly is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 9. To the extent a response is required, however, Lilly denies the allegations contained in Paragraph 9 of the Complaint.
  - 10. Lilly denies the allegations contained in Paragraph 10 of the Complaint.
  - 11. Lilly denies the allegations contained in Paragraph 11 of the Complaint.

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- 12. Lilly denies the allegations contained in Paragraph 12 of the Complaint.
- 13. Lilly denies the allegations contained in Paragraph 13 of the Complaint.

### COUNT III (Breach of Warranty)

- 14. Lilly repeats and realleges its answers contained in Paragraphs 1 through 13 above.
- 15. Lilly denies the allegations contained in Paragraph 15 as stated, but admits that following FDA approval of its Supplemental New Drug Application in 1947, Lilly manufactured and sold certain dosages of diethylstilbestrol for treatment of certain accidents of pregnancy as referenced in its product literature.
  - 16. Lilly denies the allegations contained in Paragraph 16 of the Complaint.
  - 17. Lilly denies the allegations contained in Paragraph 17 of the Complaint.
  - 18. Lilly denies the allegations contained in Paragraph 18 of the Complaint.

## COUNT IV (Misrepresentation)

- 19. Lilly repeats and realleges its answers contained in Paragraphs 1 through 18 above.
- 20. Lilly denies the allegations contained in Paragraph 20 as stated, but admits that following FDA approval of its Supplemental New Drug Application in 1947, Lilly manufactured and sold certain dosages of diethylstilbestrol for treatment of certain accidents of pregnancy as referenced in its product literature.
  - 21. Lilly denies the allegations contained in Paragraph 21 of the Complaint..
  - 22. Lilly denies the allegations contained in Paragraph 22 of the Complaint.
  - 23. Lilly denies the allegations contained in Paragraph 23 of the Complaint.

#### SECOND DEFENSE

The Complaint fails to state a claim upon which relief can be granted against Lilly.

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#### THIRD DEFENSE

The Plaintiffs' Claims are barred by the applicable statute of limitations or laches.

#### FOURTH DEFENSE

If Plaintiff sustained injuries or incurred expenses as alleged, the risks complained of by Plaintiff were not discoverable using prevailing research and scientific techniques under the then-existing state of the art and were not discoverable using procedures required by federal and state regulatory authorities charged with supervision or licensing of the product as of the time Lilly sold or otherwise parted with possession and control of the product in question.

#### FIFTH DEFENSE

If Plaintiff sustained injuries or incurred expenses as alleged, Plaintiff's claims may be barred by virtue of the intervention of a learned intermediary or intermediaries to whom defendant discharged any duty to warn.

#### SIXTH DEFENSE

This court lacks personal jurisdiction over defendant.

#### SEVENTH DEFENSE

Venue is improper in this judicial district.

#### EIGHTH DEFENSE

Lilly hereby gives notice that it intends to rely upon other and further defenses as may become available or apparent during discovery proceedings in this case, and hereby reserves the right to amend its Answer to assert any such defense.

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Respectfully submitted,

ELI LILLY AND COMPANY

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and

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Dated: August 21, 2003

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### Certificate of Service

I certify that on August 21, 2003, a true copy of Defendant Eli Lilly's Answer To The Complaint was served by U.S. First Class Mail, postage prepaid, upon:

Aaron M. Levine, Esq. Aaron M. Levine & Associates, P.A. 1320 Nineteenth Street, N.W. Suite 500 Washington, DC 20036 Attorney for Plaintiff

Lawrence H. Martin